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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0748]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Drug User Fee Cover Sheet; Form FDA 3794

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Generic Drug User Fee Cover Sheet; Form FDA 3794." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Ila S. Mizrachi,

Office of Information Management,

Food and Drug Administration,

1350 Piccard Dr.,

PI50-400B,

Rockville, MD 20850,

301-796-7726,

Ila.Mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Drug User Fee Cover Sheet; Form FDA 3794--(OMB Control Number 0910-New)

On July 9, 2012, the Generic Drug User Fee Act (GDUFA) (Public Law 112-144, Title 111) was signed into law by the President. GDUFA, designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry, requires that generic drug manufacturers pay user fees to finance critical and measurable program enhancements. The user fees required by GDUFA are as follows: A one-time fee for original abbreviated new drug applications (ANDAs) pending on October 1, 2012, (also known as backlog applications); fees for type II active pharmaceutical ingredient (API) and final dosage form (FDF) facilities; fees for new ANDAs and prior approval supplements (PASs); and a one-time fee for drug master files (DMFs).

The purpose of this notice is to solicit feedback on the collection of information in an electronic form used to calculate and pay generic drug user fees. Proposed Form FDA 3794, the Generic Drug User Fee Cover Sheet, requests the minimum necessary information to determine if a person has satisfied all relevant user fee obligations. The proposed form is modeled on other FDA user fee cover sheets, including Form FDA 3397, the Prescription Drug User Fee Act Cover Sheet. The information collected would be used by the FDA to initiate the administrative

screening of generic drug submissions and DMFs, support the inspection of generic drug facilities, and otherwise support the generic drug program. A copy of the proposed form will be available in the docket for this notice.

Respondents to this proposed collection of information would be potential or actual generic application holders and/or related manufacturers (manufacturers of FDF and/or APIs). Companies with multiple applications will submit a cover sheet for each application and facility. Based on FDA's database of application holders and related manufacturers, we estimate that 500 companies would submit a total of 3,850 cover sheets annually to pay for application and facility user fees. FDA estimates that the 3,850 annual cover sheet responses would break down as follows:[1] 2,000 facilities fees, 750 ANDAs, 750 PASs, and 350 Type II API DMFs. We also estimate that the one-time backlog fee would affect 350 application owners sponsoring 2,700 applications. The estimated hours per response are based on FDA's past experience with other submissions, and range from approximately 0.1 to 0.5 hours. The hours per response are estimated at the upper end of the range to be conservative.

In the Federal Register of July 26, 2012 (77 FR 43844), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received the following comment. Small generic manufacturers will heavily suffer from the establishment fees under GDUFA. FDA notes this comment is outside the scope of the proposed collection of information, Form FDA 3794 (Generic Drug User Fee Cover Sheet).

FDA estimates the burden of this collection of information as follows:

[1] These estimates are based on conversations between the Agency and representatives of regulated industry during the generic drug user fee negotiations.

Table 1.--Estimated Annual Reporting Burden[1]

FDA Form #	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3794[2]	500	7.7	3,850	0.5	1,925

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]For all applicable applications and fees except for the backlog fee.

The backlog fee is a one-time fee. The Agency expects the majority of these fees to be received in the first year only. The estimated reporting burden for the backlog fee is shown in table 2 of this document.

Table 2.--Estimated One-Time Annual Reporting Burden[1]

FDA Form #	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3794[2]	350	7.7	2,700	0.5	1,350

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] For backlog fee.

Dated: October 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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